

### REMARKS

Claims 1 and 3-21 are in this application and are presented for consideration. By this amendment, Applicant has amended claims 1, 3-5, 7 and 10. Claim 2 has been canceled and new claims 12-21 have been added. Specifically, the features of claim 2 have been included in claim 1. It is noted that this combination of features has been found allowable by the European Patent Office as evidenced by the attached European Patent 1 718 240 B1.

Claim 11 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended claim 10 to provide that a unilateral stitching arrangement is formed. The unilateral stitching arrangement of claim 11 now has proper antecedent basis as claim 11 is dependent upon claim 10. It is Applicant's position that the claims as now presented are clear and fully comply with the requirements of the statute. Accordingly, Applicant respectfully requests that the Examiner remove the indefiniteness rejection in light of the changes to the claims.

Claims 1-3, 5, 7, 10 and 11 have been rejected under 35 U.S.C. 102(b) as being anticipated by Debbas (U.S. 5,716,409).

The present invention relates to a hernia mesh fabric for repair of inguinal or hiatus hernias. The hernia mesh fabric comprises a base sheet of layered, flexible mesh material and a passage in the base sheet for receiving a body canal. An insertion slit is arranged between a contour of the base sheet and the passage. This advantageously allows the body canal to be

inserted into the passage. A sewing bridge is located in the vicinity of a mouth of the insertion slit and is folded down on the insertion slit to be stitched to the mesh material of the base sheet. The sewing bridge is a bridge tongue which is cut to size in one piece with the mesh material of the base sheet. The bridge tongue is integrally connected to the mesh material of the base layer. The fact that the bridge tongue is integrally connected to the mesh material is a significant feature of the present invention because it advantageously provides for a simple and easy way of closing the insertion slit. This advantageously ensures secure and reliable closure of the insertion slit so that the fabric is maintained around the body canal and does not come loose. The prior art as a whole fails to disclose such features and such simple connection advantages.

Debbas fails to teach and fails to suggest the combination of a sewing bridge that is integrally connected to mesh material of a base sheet as claimed. Debbas discloses a mesh material 10 having a passageway 12 wherein a flap 16 is provided. However, the flap 16 is separate from the mesh material 10 and is not integrally connected to the mesh material 10 as claimed. This is a significant departure from the present invention since this disadvantageously requires that the flap 16 of Debbas be connected to the mesh material 10 via complicated process steps, such as suturing, stapling, gluing, bonding or welding the flap 16 to the mesh material 10. This disadvantageously takes a lot of time to connect the flap 16 of Debbas to the mesh material 10 since the flap 16 is small and requires skillful hands to attach the flap 16 to the mesh material 10. Compared to Debbas, the present invention advantageously avoids such complicated methods of connecting the sewing bridge to the mesh material. According to the

present invention, the complete hernia mesh, including the base sheet and the sewing bridge, is cut out in one piece from mesh material. This advantageously allows the base sheet and the sewing bridge to be one integral structure. This is significant in the present invention because there is no need for a separate handling of the sewing bridge since the sewing bridge can be simply folded over onto the slit and attached to the base sheet. In contrast to the present invention, Debbas fails to disclose such simple sewing bridge connection advantages since Debbas does not teach or suggest that the flap 16 is integrally connected to the mesh material 10 as featured in the present invention. As such, the prior art as a whole takes a completely different approach and fails to teach or suggest each and every feature of the claimed combination. Accordingly, Applicant respectfully requests that the Examiner favorably consider claim 1 as now presented and all claims that depend thereon.

Claim 4 has been rejected under 35 U.S.C. 102(b) as anticipated by Debbas, or in the alternative, under 35 U.S.C. 103(a) as obvious over Debbas in view of Bardeau (FR 2 744 906).

As previously discussed above, Debbas fails to teach or suggest the combination of a base sheet of mesh material and a sewing bridge that is integrally connected to the mesh material of the base sheet. Bardeau also fails to provide any teaching or suggestion for the combination of mesh material that is integrally connected to a sewing bridge as claimed. Bardeau merely discloses a panel having a flexible rectangular sheet with a central opening 2 and a slot 5 and a wing 3 that is superimposed on a part of the panel to cover the slot 5. However, the wing 3 of Bardeau is not integrally connected to the panel as claimed. Bardeau

clearly discloses that a connection 4 between the panel 1 and the wing 3 is by means of gluing, welding or suturing (see page 3, line 30). As such, the wing 3 of Bardeau is not integrally connected to the panel as claimed. Accordingly, all claims define over the prior art as a whole.

Claim 6 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Debbas in view of Therin et al. (U.S. 2002/0013590).

As already discussed above, Debbas does not teach or suggest essential features of the present invention. Therin et al. does not teach and does not suggest the combination of a sewing bridge that is integrally connected to mesh material of a base sheet as claimed. Therin et al. merely discloses that the flap 3 is a separate piece that is attached to a reinforcement piece 2 by means of a stitch or a seam 7. This disadvantageously requires a complicated method of connecting the flap 3 to the reinforcement piece 2. Compared with Therin et al., the sewing bridge of the present invention is integrally connected to the mesh material of the base sheet. This advantageously allows the sewing bridge to be easily folded over on the slit and stitched. In contrast to the present invention, Therin et al. does not disclose such simple connection advantages since the flap 3 is not formed in one piece with the reinforcement piece 2. As such, the prior art as a whole takes a completely different approach. Accordingly, all claims define over the prior art as a whole since the cited references fail to establish a prima facie case of obviousness.

Claims 8 and 9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Debbas in view of Wilberg (DE 198 32 634).

Although Wilberg teaches a multilayer flat implant for hernia treatment, the references

as a whole fail to suggest the combination of features claimed. Specifically, the references as a whole provide no suggestion or teaching for the combination of a sewing bridge that is integrally connected to mesh material of a base sheet. As such, the references together do not teach or suggest the combination of features claimed. One of ordinary skill in the art is presented with various concepts, but these concepts do not provide any direction as to combining the features claimed. All claims define over the prior art as a whole.

Applicant has added new claims 12-21. New independent claims 12 and 21 provide for similar features as found in amended claim 1, but in different claim language. Claims 12 and 21 highlight that an appendage is integrally connected to mesh material of a base sheet with the appendage being movable from an unfolded position to a folded position. The appendage is stitched to the mesh material in the folded position. The prior art as a whole fails to disclose such features. New dependent claims 13-20 have been added to further clarify the features of the invention. Applicant respectfully requests that the Examiner favorably consider new claims 12-21.

Favorable consideration on the merits is requested.

Respectfully submitted  
for Applicant,

A handwritten signature in black ink, appearing to read 'J. McGlew', with a stylized flourish at the end.

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Attached: Copy of EP 1 718 240 B1  
Petition for One Month Extension of Time

JJM:BMD  
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